REMARKS

Election/Restrictions

Pursuant to the final restriction requirement, Applicant has deleted X "is NR_3 " Claim 1 as amended thus recites "X is oxygen," consistent with Group I as set forth by the Examiner.

Specification

Pursuant to the Examiner's objection of the abstract of the disclosure, Applicant submits herewith an abstract that is presented on a separate sheet, apart from any other text.

Claim Rejections 35 USC 112/101

Claims 1 and 3-6 have been rejected as being indefinite. In response, Applicant has deleted the term "methylenedioxy derivatives thereof" from Claim 1 and also has deleted the recitation "R6 may be a moiety of formula I."

Claims 1-5 have been rejected as indefinite. In response, Applicant has amended Claims 1-5 to recite respective methods of treating and manufacturing.

Claims 1,2 and 4-6 were rejected for lack of enablement. Applicant traverses this rejection. Claim 1 is limited to a 'patentably distinct' invention. The member compounds of the group defined by the formula (I) in Claim 1 as amended are galantamine and its derivatives that share a common skeleton and are structurally similar to galantamine to a sufficient extent to be reasonably regarded as enabled by the disclosure and data in respect of galantamine provided in the application, for combating attention deficit disorders. Claim 2 by formula (II) defines a more limited group of compounds than formula (I), whereas Claims 4 and 5 define preferred types of 'attention deficit disorders' to be treated

It should be appreciated that the effect in combating attention deficit disorders is derived from the functional ability of galantamine and its defined derivatives to inhibit acetylcholinesterase selectively at nicotinic receptor sites and ability to cross the blood-brain barrier. Claims 1-3 were amended to more clearly emphasize that galantamine derivatives used in the method are acetylcholinesterase inhibitors that are active selectively at nicotinic receptor sites and capable of crossing the blood-brain barrier. Thus, the claims are enabled not only by their structural similarity to galantamine, but also functionally by their ability to inhibit acetylcholinesterase, selectivity to nicotinic receptor sites and ability to cross the blood-brain barrier, like galantamine.

To the extent that Claims 1-3 as filed were believed by the Examiner to encompass derivatives that are not functionally equivalent to galantamine – that has been overcome with the current amendment, which specifies that

"galantamine derivatives" are limited to those that are functionally equivalent to galantamine.

The Examiner, applying the *Wands* factors has stated that the "scope of the compounds claimed to be useful is extremely broad" and that "all the guidance provided by the specification ... is directed to merely ... galantamine." Applicants respectfully disagree with the Examiner's position and asssert that they are entitled to the scope of protection as claimed. Having taught and enabled the use of galantamine, it is reasonable for those of skill in the art to expect that functionally equivalent derivatives of galantamine to be similarly effective. Functional equivalence in terms of selectivity for acetylcholinesterase can readily be determined by the selectivity test indicated on pages 6 to 7 of the specification. Further, galantamine is known to be capable of crossing the blood-brain barrier, and the skilled person can easily determine whether a particular derivative can also cross the blood-brain barrier. Therefore, the specification provides a person of ordinary skill in the art with sufficient guidance to enable functional equivalence to galantamine to be determined so as to define derivatives that are, like galantamine, effective against attention deficit disorders.

In light of the foregoing, Applicants maintain that the instant specification enables one of ordinary skill in the art to practice the invention as claimed without undue experimentation.

Claim Rejections 35 USC 103

Claims 1-6 have been rejected over Snorrason (WO92/20328) in view of Gliichi (EP0607864). Applicants respectfully traverse this rejection. Snorrason discloses use of galantamine for counteracting the sedative or hypnotic or respiratory depressive effects of benzodiazepines. Benzodiazepines may be given for treatment of diseases such as hyperactivity in children. However, as appears to be acknowledged by the Examiner, Snorrason does not disclose or teach that galantamine can be used to treat attention deficit disorders such as ADHD in children. Snorrason is therefore only of relevance in so far as it discloses that galantamine and its derivatives are acetylcholinesterase inhibitors.

Giichi discloses that certain tricyclic compounds have cholinesterase inhibitory activity and monoamine reuptake inhibitory activity and may therefore have antiamnestic and antidepressant activity (see page 71 lines 35-39). Giichi postulates that the tricyclic compounds may be useful for treating senile dementia, Alzheimer's Disease, Huntington's chorea, hyperkinesis and mania (see page 71 lines 48-50), in particular senile dementia, Alzheimer's Disease (see Claims 30, 31, 33).

In the absence of definition or context, "hyperkinesis" as such refers only to abnormally increased muscular movements or spasms. No mention or suggestion of treating attention deficit disorders can be found in Giichi.

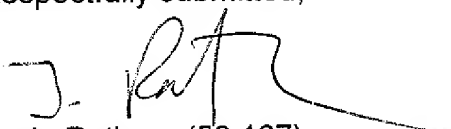
Moreover, the example data in Giichi demonstrate only that the tricyclic compounds have cholinesterase inhibitory activity and monoamine reuptake inhibitory activity. Giichi provides no rationale as to why the compounds might be useful to treat Huntington's chorea, hyperkinesis and mania, i.e. whether due to their cholinesterase inhibitory activity, due to their monoamine reuptake inhibitory activity, or due to some other activity of the tricyclic compounds.

Giichi is therefore not enabling in respect of the treatment of hyperkinesis. Furthermore, Giichi does not suggest that cholinesterase inhibitors generally would be useful to treat hyperkinesis, let alone acetylcholinesterase inhibitors such as galantamine and its derivatives as defined by formula (I) in Claim 1. In any case, since "hyperkinesis" may have a variety of etiologies, the single mention of "hyperkinesis" in Giichi does not imply treatment of "attention deficit disorders".

In light of the above, and in the absence of a suggestion to combine Snorrason with Giichi, the invention as set forth in the claims as amended is patentable over the cited art.

In light of the above arguments and amendments, Applicants believe that the application is in condition for allowance.

Respectfully submitted,



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